Kathi Vidal, Director
U.S. Patent and Trademark Office
Alexandria, VA 22314

June 20, 2023

RE: Docket No. PTO-P-2020-0022, **Changes Under Consideration to Discretionary Institution Practices**

Director Vidal:

On behalf of U.S. PIRG, UAEM and Public Citizen, we are submitting comments on the U.S. Patent and Trademark Office Advanced Notice of Proposed Rulemaking (ANPRM) on discretionary denials and other matters relating to patent challenges through the Patent Trial and Appeal Board (PTAB), published April 21, 2023 in the Federal Register.[1] We urge the U.S. Patent and Trademark Office (PTO) to **withdraw the ANPRM in its entirety** because of the dramatic negative impact it will have on the public's ability to use the Patent and Trial Board to challenge the validity of patents. The rules are an overreach, proposing changes to several important statutorily-defined elements including standing, standards of proof, and barring new claims because of prior decisions. If changes are needed to ratchet back any abuse of the PTAB that are not sufficient in the PTO's existing power, the Director should clearly document specific evidence of that abuse and ask Congress to amend the law to give the PTO greater power to deny certain petitions to the PTAB.

Two-thirds of U.S. adults rely on prescription medication.[2] And yet 1 in 4 people struggle to pay for them.[3] Affordability has become a growing problem as pharmaceutical companies are raising prices. The U.S. Department of Health and Human Services has documented this issue:

- "In January 2022, the average list price increase was nearly $150 per drug (10%), and in July 2022, it was $250 (7.8%).
- Several drugs increased their list prices by more than $20,000 or by more than 500%.
- There were 1,216 products whose price increases during the twelve-month period from July 2021 to July 2022 exceeded the inflation rate of 8.5% for that time period. The average price increase for these drugs was 31.6%."[4]

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[1] Federal Register, 88 FR 24503, https://www.federalregister.gov/documents/2023/04/21/2023-08239/changes-under-consideration-to-discretionary-institution-practices-petition-word-count-limits-and#addresses.

[2] Emily Ihara, "Prescription Drugs", Georgetown University Health Policy Institute, https://hpi.georgetown.edu/rxdrugs/#:~:text=More%20than%20131%20million%20people,United%20States%20%E2%80%94%20use%20prescription%20drugs

[3] Ashley Kirzinger et al., "Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say it's Difficult To Afford Their Medicines, Including Larger Shares Among Those With Health Issues, With Low Incomes and Nearing Medicare Ages", KFF, March 1, 2019, https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/

[4] U.S. Dept of Health and Human Services, "New HHS Reports Illustrate Potential Positive Impact of Inflation Reduction Act on Prescription Drug Prices," Sept. 30, 2022, https://www.hhs.gov/about/news/2022/09/30/new-hhs-reports-illustrate-potential-positive-impact-inflation-reduction-act-prescription-drug-prices.html

Without competition in the prescription drug market, these price increases are rising unchecked. But the Biden administration announced its desire to address the lack of competition:

> "..too often, patent and other laws have been misused to inhibit or delay — for years and even decades — competition from generic drugs and biosimilars, denying Americans access to lower-cost drugs."[5]

And the President's Executive order went on to recommend agency action that would:

> "...ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law."

The Executive Order intended for agencies to support efforts that would ensure patents have only been granted for innovations that are truly novel and non-obvious. Yet, contrary to this laudatory goal, this ANPRM dramatically narrows the public's ability to challenge the validity of patents through the cost-effective, swift "second-look" by the expert panel of judges in the PTAB process and the proposed rules significantly increase the public's burden to petition for PTAB review.

The PTO impacts drug pricing.

The PTO plays a very important role in determining whether or not prescription drugs face competition. Patents grant patent-holders a 20 year market exclusivity which blocks entry of generic and biosimilar alternatives. Patent approvals therefore can directly impact the cost of prescriptions. The longer the market exclusivity, the longer patients wait for the cost-savings brought by generic and biosimilar competition. Wrongly-granted patents are even more detrimental if they unnecessarily prevent competitors from selling therapeutically equivalent medications to patients.

High prices impact all insured people, not just those needing medication. Because drug expenses make up 20% of our insurance costs; high drug prices increase our insurance premiums.[6] Employers struggle to keep health premiums affordable for their workers. And high drug prices drive up costs for important taxpayer-funded health programs like Medicare and Medicaid. High drug prices cause negative health impacts when people are forced to make financial choices as to whether they can pay for the medicines they need: families sometimes must choose to leave a prescription unfilled or skip their prescribed dosage.[7,8]

While brand-name drugs make up only 8% of prescriptions, they account for 84% of all U.S. drug spending.[9] But when generics and biosimilars enter the market, the competition drives down prices and

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[5] White House, "Executive Order on Promoting Competition in the American Economy," July 9, 2021, https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/

[6] AHIP, "Your Health Care Dollar: Vast Majority of Premium Pays for Prescription Drugs and Medical Care", Americas Health Insurance Plans, Sept. 6, 2022, https://www.ahip.org/news/press-releases/your-health-care-dollar-vast-majority-of-premium-pays-for-prescription-drugs-and-medical-care

[7] See note 3.

[8] Robin A. Cohen, Maria A. Villarroel, *Strategies Used by Adults to Reduce Their Prescription Drug Costs: United States, 2013*, National Center for Health Statistics, January 2015, https://pubmed.ncbi.nlm.nih.gov/25633356/.

[9] IQVIA Institute for Human Data Science, *The Use of Medicines in the U.S. 2022*, April, 2022, 39, https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2022.

savings are dramatic - $10-20 billion annually.[10] The FDA's own data show that with even just one generic alternative, you can bring prices for that drug down by as much as 40%.[11] That's the power of a competitive marketplace.

Some drug companies abuse the patent system.
Patents are meant to spur innovation, and the monopoly-pricing granted by a patent isn't meant to last forever. Today's drug makers spend significant time and money[12] obtaining new patents for minimal adjustments, like dosing, delivery or manufacturing changes for medications already on our pharmacy shelves. When pharmaceutical companies misuse the patent system by wrapping drugs in patent thickets, they undermine price competition by blocking patient access to generics and biosimilars.[13] PTO processes can have a huge influence on whether a lower cost alternative is ever offered to patients. It's imperative that those processes are designed to ensure only high quality patents are approved. Because patent examiners can make mistakes, there needs to be accessible ways to challenge patent approvals.

Although a wrongly-granted patent can be challenged in federal courts, these challenges take years and come with a median cost of $3.5 million per case.[14] And not everyone can bring a patent challenge to federal court. Only those who can demonstrate that it faces a concrete threat from the patent can bring a case.[15]

Ten years ago, Congress recognized the drawbacks of litigation as a means for re-examining patent approvals. Through overwhelming bipartisan support, Congress passed the America Invents Act (AIA) to ensure that there was a swifter and less costly way of challenging the validity of patent claims.[16] The law established efficient and affordable proceedings through the PTAB and gave "anyone" the right to bring these challenges.

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[10] Ryan Conrad PhD et al., "Estimating Cost Savings from New Generic Drug Approvals in 2018, 2019, and 2020", US Food and Drug Administration, August 2022, https://www.fda.gov/media/161540/download
[11] FDA, Generic Competition and Drug Prices, https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices
[12] Kristi Martin, "House Oversight Committee's Investigations into Drug Pricing Highlight Need for Reform", Commonwealth Fund, April 30, 2021, https://www.commonwealthfund.org/blog/2021/house-oversight-committees-investigations-drug-pricing-highlight-need-reform
[13] U.S. PIRG, "The Cost of Prescription Drug Patent Abuse", April 19, 2023, https://pirg.org/resources/the-cost-of-prescription-drug-patent-abuse/
[14] These numbers reflect cases with $10-$25 million at risk and include pre- and post-trial costs. Malathi Nayak, "Costs Soar for Trade Secrets, Pharma Patent Suits, Survey Finds", Bloomberg Law, September 10, 2019, https://news.bloomberglaw.com/ip-law/costs-soar-for-trade-secrets-pharma-patent-suits-survey-finds
[15] Stronger Patents Act of 2019, H.R. 3666, S. 2082; see Stronger Patents Act of 2019, Patently-O Blog, Sept. 10, 2019, https://patentlyo.com/patent/2019/09/stronger-patents-2019.html (describing provisions)
[16] 35 U.S. Code § 314

The PTAB has been effective in challenging drug patents.
Since 2012, more than 1,000 challenges have been brought before the PTAB against pharmaceutical and biologic patents.[17] And PTAB patent challenges have been reliable: More than 90 percent of PTAB decisions that were reviewed on appeals by the Federal Circuit were upheld.[18]

The accessible and efficient PTAB process is essential to challenge patents and clear the pathway for earlier entry of competing products that can help lower drug costs. Recent analysis of drug patent challenges before the PTAB found that "a large fraction of patents challenged this way are deemed unpatentable at both the agency and appellate levels."[19] Importantly, this analysis goes on to show that "administrative cancellation of drug patents correlates closely with subsequent generic drug competition and reduced drug prices."[20] The report offers case studies of PTAB decisions to support this statement; here are two examples.

- Suboxone: (used to treat opioid use disorder) IPR decisions combined with other litigation allowed at least 13 generic competitors to enter the market. Prices dropped by 50%.[21]
- Solostar Insulin Injector Pen: The patent office found the patents were so similar to other insulin injectors already on the market that the patents should never have been granted. Prices dropped by 65%.[22]

However, beginning in 2016, the PTAB established new internal processes to review petitions for a patent challenge through its policy of discretionary denials.[23] Since then it has gotten more difficult to use the process. Discretionary denials increased dramatically, from only six during 2016 to 84 in 2019 and 167 in 2020.[24]

> **The proposed rules contemplated by this ANPRM would create unnecessary barriers to instituting a patent challenge, undoing the value of the PTAB as statutorily designed in the AIA.**

Withdraw the ANPRM in its entirety.
We anticipate these proposed changes, if adopted as a rule, will increase the number of discretionary denials which means that fewer patents will be heard by the PTAB and fewer bad patents will be weeded out. The ANPRM would severely limit the PTAB as a lower cost, accessible way for anyone to strike invalid

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[17] U.S. PTO, "PTAB Orange Book patent/biologic patent study FY21 Q3" June 2021 Update, https://www.uspto.gov/sites/default/files/documents/PTABOBbiologicpatentstudy8.10.2021draftupdatedthruJune2021.pdf
[18] Mathew G. Sipe, EXPERTS, GENERALISTS, LAYPEOPLE — AND THE FEDERAL CIRCUIT, Harvard Journal of Law & Technology Volume 32, Number 2 Spring 2019, https://jolt.law.harvard.edu/assets/articlePDFs/v32/32HarvJLTech575.pdf
[19] Charles Duan, "On the Appeal of Drug Patent Challenges", April 17, 2023, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4406404
[20] See note 18.
[21] See note 18, p. 25.
[22] See note 18, p. 26.
[23] I-MAK, "Lowering Prescription Drug Costs by Removing Barriers to Challenging Patents," Nov. 2021, https://www.i-mak.org/wp-content/uploads/2021/11/Removing-Barriers-to-Challenging-Patents-to-Help-Lower-Prescription-Drug-Costs-2021-11-30F.pdf
[24] Unified Patents, "PTAB Discretionary Denials Up 60%+ in 2020: Fueled Entirely by 314(a) Denials," Jan. 5, 2021 https://www.unifiedpatents.com/insights/2020-ptab-discretionary-denials-report

patents. Those with valid patents have nothing to fear from a PTAB review; only those with wrongly-granted patents should fear a second-look.

For these reasons, we urge you to withdraw the ANPRM:

The public interest: the PTAB is the only venue for "any person" to challenge patent validity. The federal courts are closed to members of the public who want to challenge patent validity. Yet, if invalid patents are allowed to stand, the market exclusivity guaranteed by that bad patent will dramatically impact the public by blocking competitors who could offer lower cost prescription drugs. In the AIA, Congress explicitly allows "any person" to petition for review of a patent, yet the PTO is proposing to deny challenges by those without standing to sue in district court. The AIA's co-author, former Senator Patrick Leahy clarified that in writing the legislation there was no desire to limit who could bring a challenge. "The reason was that each petition should be heard on the merits and decided on the validity of the patent, not based on who filed a petition for review."[25]These new proposed standing requirements will shut out individuals and organizations from challenging patents for the benefit of others – for example, to clear out patent thickets impeding access to medicine or medical devices. These requirements will not improve patent quality or promote innovation; they will simply protect invalid patents from meritorious challenges. **The PTO should not implement a "standing" requirement.**

The standard of proof: patent challengers need only show a "reasonable likelihood" that a granted patent is invalid: Congress established this standard, yet the PTO is effectively rewriting the law to raise the threshold to require petitions that are "compelling" on the merits. "Reasonable likelihood" is an established standard with a definition well-understood. "Compelling merits", undefined, clearly requires more than Congress intended and will give the PTAB more opportunity to deny the challenger a chance to bring the patent under the review of the patent expert judges. **The PTO should not raise the standard of proof.**

Previous or ongoing challenges on the same claims: the PTO can consider patent challenges even if district courts have considered other grounds of invalidity. The AIA protects patent owners from nuisance challenges when a patent challenge relies on the same or similar grounds raised in district court. But under the proposed rules, even if for example new 'prior art' discoveries are made that have a "reasonable likelihood" of proving a patent is invalid, that challenge would be barred if a decision on that patent claim had already been made. **The PTO should not bar new patent challenges that have a reasonable likelihood of success, regardless of previous decisions relating to that claim.**

We strongly urge you to withdraw your ANPRM as it will significantly narrow the ability to challenge the validity of approved patents. The AIA has played a key role by offering a less expensive and quicker resolution to patentability challenges. And importantly, the AIA provided the public an opportunity to challenge weak patents, a right not allowed to the public in federal district court. The benefits of AIA proceedings cannot be overstated. In 2015, the Congressional Budget Office determined that less drastic

[25] "Leahy: New USPTO rulemaking should seek to strengthen, not weaken, the America Invents Act", The Hill, May 25, 2023, https://thehill.com/opinion/congress-blog/4020170-leahy-new-uspto-rulemaking-should-seek-to-strengthen-not-weaken-the-america-invents-act/

restrictions on AIA proceedings than those proposed now would cost U.S. taxpayers over $1 billion in higher drug prices.[26]

We would instead recommend pursuing policies that will support efforts to cull anti-competitive patent thickets of wrongly-granted patents, such as eliminating patent fees for low-resources, nonprofits who want to use the PTAB, increase transparency to aid researchers in their efforts to further improve the patent approval process , and increase patent examiner time and other policies that increase competition to lower drug prices.

Respectfully submitted,

U.S. PIRG is a 50 year old nonprofit consumer advocacy organization with state affiliates in 24 states.. We speak out for a healthier, safer world which includes promoting policies that support the delivery of the high value healthcare we deserve.

UAEM is a student-driven nonprofit organization made up of researchers, future physicians, and future attorneys focused on addressing the access to medicines crisis in the U.S. and around the world. Two-thirds of U.S. adults rely on prescription medication.

Public Citizen is a consumer advocacy organization based in Washington, DC with a fifty year history advocating for the public interest before Congress, the courts and federal agencies.

[26] Joseph Walker, "Drug Industry Rule would raise Medicare Costs", Wall Street Journal, August 31, 2015 https://www.wsj.com/articles/drug-industry-bill-would-raise-medicare-costs-1441063248